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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,228	04/24/2001	Stanley Stewart Davis	8567-604US(WESR/P21724US)	6578

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EXAMINER

HOWARD, SHARON LEE

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,228

Applicant(s)

DAVIS ET AL.

Examiner

Sharon L. Howard

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2002 and 21 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Examiner acknowledges receipt of one month extension of time and notice of appeal filed on 8/15/02 and request under 1.114 and Preamendment B with attachment filed on 10/21/02.

Claims 1,2 and 9 have been amended.

Claim 8 has been cancelled.

New claims 15-17 have been added.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7,9-11 and newly added claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins ('728) in view Woods ('425).

Collins discloses a composition and method for treating pain and Parkinson's disease, other inflammatory diseases (col.2, lines 1-29), flurbiprofen and ibuprofen (col.29, lines 12 and 13), non-steroidal anti-inflammatory diseases (col.30, lines 52-67 and col.31, lines 1-12). Collins teaches pharmaceutical compositions which are known to be in the form of an emulsion (col.26, lines 33-35) and COX2 inhibitors (col.32, line 26). Collins teaches salicylic acid derivatives, propionic acid derivatives, acetic acid derivatives, fenamic acid derivatives, carboxylic acid derivatives, butyric acid

derivatives, oxicams, pyrazoles and pyrazalones having similar analgesic and anti-inflammatory properties (col.28, lines 38-67, col.29, lines 1-67, col.30, lines 1-47).

Collins does not teach hydroxylated oil.

However, Woods teaches a hydroxylated oil, castor oil (col.11, lines 14-23) which is known in pharmaceutically acceptable emulsions, and it is known in the art that the oil provides solubilization of the drug. Woods also teaches pharmaceutical compositions comprising emulsions (col.9, lines 65-67, bridging col.10, line 1), vegetable oils (col.10, line 7) and COX-1 and COX-2 (col.9, lines 23-25 and EXAMPLES at col.13).

Woods discloses that it is known in the art that the amount of drug to be used will depend upon the route of administration, the severity of the condition being treated and the activity of the particular compound. Woods also teaches that it is known in the art to first use small amounts of the drug than the required amount in order to achieve the desired therapeutic effect of the drug, and then to gradually increase the amount of the drug until the desired effect is obtained (col.11, lines 66-67 and col.12, lines 1-20).

Response to Arguments

Applicant's arguments filed 10/21/02 have been fully considered but they are not persuasive. Applicant argues that the Collins composition does not contain a drug for use in the treatment of impotence. Collins does not teach which phase of "an emulsion" the IL-1 inhibitor of Collins or any other of the active agents may be suspended, nor does it teach that an oil phase of the Collins emulsion contains more than 50% of the active agent dissolved therein.

In response to applicants' arguments, the amount of the drug would not impart patentability and a composition is being claimed, the future use would only be important in a process claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3121 for regular communications and (703) 305-3592 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Sharon Howard
January 7, 2003



THURMAN K. PAGE
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